

Ethicon Endo-Surgery, LLC

510(k) Premarket Notification (Special) for Harmonic
ACE14S, ACE23E and ACE36E**Special 510(k) Summary****Company
Information**Ethicon Endo-Surgery, LLC
4545 Creek Road
Cincinnati, OH 45242**OCT 24 2013****Contact
Information**David M. Locke
Regulatory Affairs Associate, Energy
Ethicon Endo-Surgery
(419) 233 – 2611 ext. 1281
dlockel@its.jnj.com**Date Prepared** Aug 09, 2013**Device Name**

Trade Names:

- HARMONIC ACE Curved Shears with Scissor
- HARMONIC ACE Curved Shears with Ergonomic Handle

Classification Name:

Instrument, Ultrasonic Surgical

Common Name:

Ultrasonic scalpel

Device Class Unclassified**Panel** General & Plastic Surgery**Product Code** LFL**Classification
Regulation** Unclassified

Predicate Device Information	<p>The Predicate devices are:</p> <ul style="list-style-type: none"> ○ Harmonic ACE curved Shears with Scissor Handle and Hand Control cleared under K051036 & K060245 ○ Harmonic ACE Curved Shears with Pistol Handle and Hand Control cleared under K051036 & K060245
Device Description	<p>The Harmonic ACE Curved Shears with Scissor Handle (ACE-S) is a sterile, single patient use, ultrasonic surgical instrument consisting of a scissor handle housing assembly with hand control buttons, a rotating shaft with a curved, ultrasonic blade and a clamp arm on a 14 cm length shaft. The handle housing has an integrated audible/tactile mechanism for indicating full closure. The instrument is designed for use in open or laparoscopic procedures. The Harmonic ACE instruments are used for the coagulation of vessels up to and including 5mm in diameter.</p> <p>The Harmonic ACE Curved Shears with Ergonomic Handle (ACE-E), Hand Control are sterile, single patient use, ultrasonic surgical instruments consisting of an ergonomic housing assembly with hand control buttons, a rotating shaft with curved, ultrasonic blades and clamp arms. The handle housing has an integrated audible/tactile mechanism for indicating full closure. The instruments are designed for use in open or laparoscopic procedures and are available in various shaft lengths. The Harmonic ACE instruments are used for the coagulation of vessels up to and including 5mm in diameter.</p>
Description of Changes to the Device	<p>There have been minor design and labeling changes to the ACE-S and the ACE-E Harmonic instruments since the clearance of K051036 and K060245 respectively. None of these changes required notification to the agency per FDA guidance document: <i>Deciding When to Submit a 510(k) for a Change to an Existing Device (K97-1)</i>. These changes are being incorporated in this submission to provide the Agency with information for the most current version of these devices.</p> <p>The Harmonic ACE-E instruments were changed from a pistol grip handle design to a handle with a more ergonomic design with activation buttons positioned in a more accessible location. The 14 cm length shaft continues to use the ACE-S scissors handle. Additional minor design changes for manufacturability and user ease of assembly were implemented. Changes were verified and validated in accordance with design control requirements. Labeling for the ACE-E and ACE-S instruments was updated to show the device with the ergonomic handle and to enhance warnings and precautions. There has been no change in intended use.</p>

Intended Use	The Harmonic Shears are indicated for soft tissue incisions when bleeding control and minimal thermal injury are desired. The instrument can be used as an adjunct to or substitute for electrosurgery, lasers, and steel scalpels in general, plastic, pediatric, gynecologic, urologic, exposure to orthopedic structures (such as spine and joint space), and other open and endoscopic procedures.
Completion of Design Control Activities	The Ethicon Endo-Surgery design control procedures were followed to develop and test the minor modifications. The devices continue to meet predetermined acceptance criteria. Design verification and validation testing revealed no new issues of safety and efficacy related to the changes.
Performance Data	Preclinical porcine vessel sealing validation studies demonstrated equivalent performance following handle modifications. Preclinical study criteria for success included the following parameters: transection times, hemostasis, thermal spread measurements and blood pressure challenges on sealed vessels. Additionally, functionality and reliability testing was performed to demonstrate that the subject devices meet design requirements following device modifications. No clinical studies were required to support a finding of substantial equivalence. In conclusion, the testing results demonstrate that the ACE-E and ACE-S devices are as safe and effective as the predicate devices. The results from testing support the substantial equivalence of the ACE-E and the ACE-S devices to the predicate devices.
Substantial Equivalence	The modified devices are substantially equivalent to the unmodified predicate devices in that they have the same intended use as the predicate devices and the same technological characteristics that do not raise different types of questions of safety and effectiveness. The modification to a more ergonomic handle does not adversely affect the hemostatic capability of the devices. Testing shows the modified Harmonic Instruments seal vessels up to and including 5 mm as did the predicate Harmonic devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

Ethicon Endo-Surgery, LLC
Mr. David Locke
Regulatory Affairs Associate, Energy
4545 Creek Road
Cincinnati, Ohio 45242

October 24, 2013

Re: K132512
Trade/Device Name: HARMONIC ACE Curved Shears
Regulatory Class: Unclassified
Product Code: LFL
Dated: October 18, 2013
Received: October 21, 2013

Dear Mr. Locke:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use510(k) Number (if known): K132512

Device Names:

- HARMONIC ACE Curved Shears with Scissor Handle
- HARMONIC ACE Curved Shears with Ergonomic Handle

Indications for Use:

The Harmonic Shears are indicated for soft tissue incisions when bleeding control and minimal thermal injury are desired. The instrument can be used as an adjunct to or substitute for electrosurgery, lasers, and steel scalpels in general, plastic, pediatric, gynecologic, urologic, exposure to orthopedic structures (such as spine and joint space), and other open and endoscopic procedures.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE
IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Long H.
Chen -A

Digitally signed by Long H. Chen -A
DN: cn=US, ou=U.S. Government, ou=HHS,
ou=FDA, ou=People, cn=Long H. Chen -A
0.9.2342.19200300.100.1.1=1300369056
Date: 2013.10.24 09:16:13 -0400

for MXM

(Division Sign-off)

Division of Surgical Devices

510(k) Number: K132512

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